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Certifier D. Hawkins

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0539]

Edwin Kokes; Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Edwin Kokes from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Kokes was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Mr. Kokes failed to request a hearing and, therefore, has waived his opportunity for a hearing concerning this action.

DATES: This order is effective [insert date of publication in the FEDERAL REGISTER].

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Carol Drew,

Center for Drug Evaluation and Research (HFD-7),

Food and Drug Administration,

cd0354

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NFR-1

5600 Fishers Lane,

Rockville, MD 20857,

301-594-2041.

SUPPLEMENTARY INFORMATION:

I. Background

On August 19, 1998, the U.S. District Court for the District of Nebraska entered judgement against Mr. Kokes for one count of mail fraud, a Federal felony offense under 18 U.S.C. 1341. This offense was committed as part of a health care fraud scheme involving the sale of unapproved drug products to patients.

As a result of this conviction, FDA served Mr. Kokes by certified mail on July 31, 2002, a notice proposing to permanently debar Mr. Kokes from providing services in any capacity to a person that has an approved or pending drug product application. The proposal also offered Mr. Kokes an opportunity for a hearing on the proposal. The debarment proposal was based on a finding, under section 306(a)(2)(B) of the act (21 U.S.C. 335a(a)(2)(B)), that Mr. Kokes was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Mr. Kokes was provided 30 days to file objections and request a hearing. Mr. Kokes did not request a hearing. His failure to request a hearing constitutes a waiver of his opportunity for a hearing and a waiver of any contentions concerning his debarment.

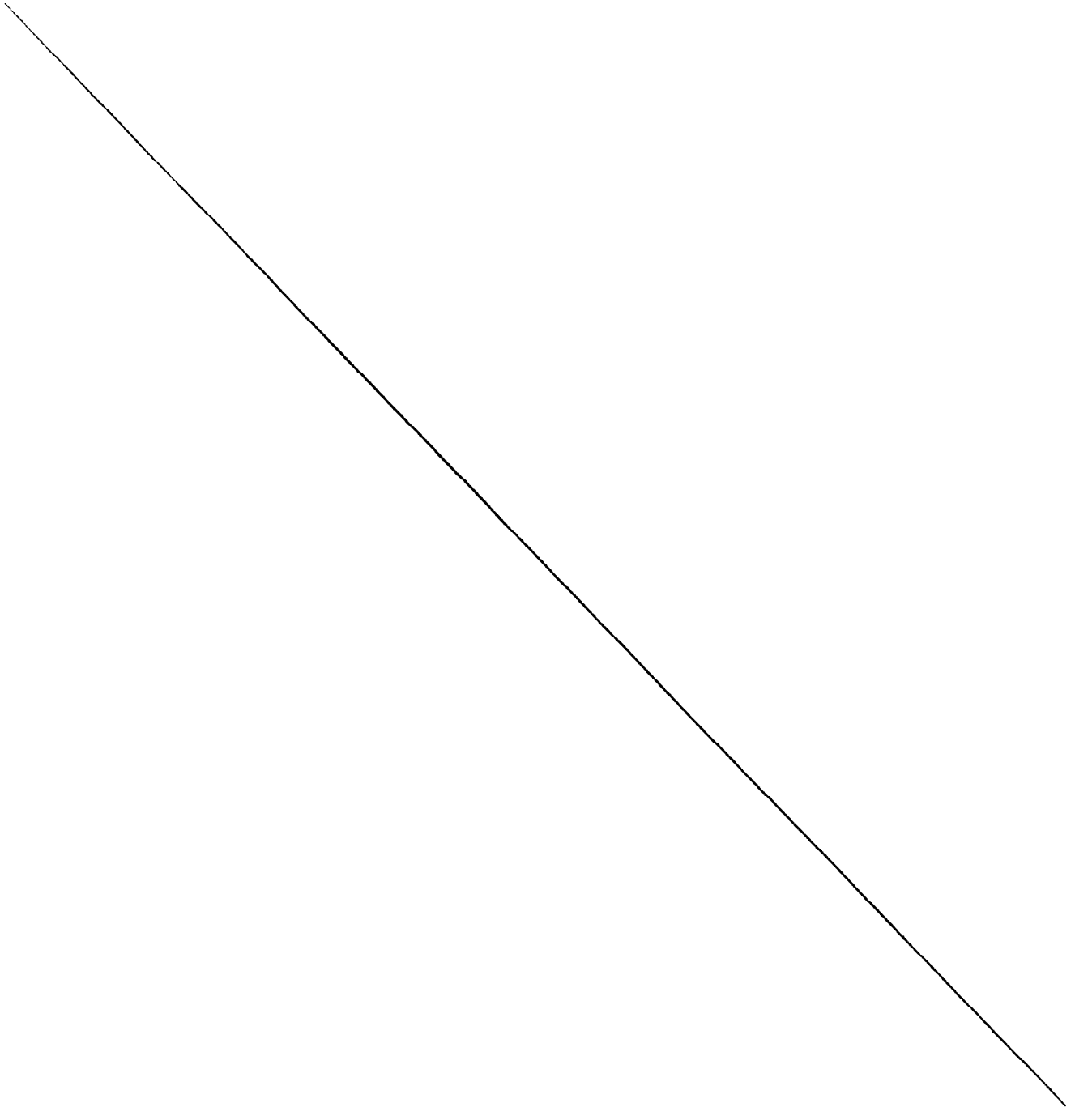
II. Findings and Order

Therefore, the Director, Center for Drug Evaluation and Research, under section 306(a)(2)(B) of the act, and under authority delegated to her (21 CFR 5.34), finds that Mr. Edwin Kokes has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act.

As a result of the foregoing finding, Mr. Edwin Kokes is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382) or under section 351 of the Public Health Service Act (42 U.S.C. 262)(see sections 306(c)(1)(B) and (c)(2)(A)(ii) and 201(dd) of the act (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application who knowingly uses the services of Mr. Kokes, in any capacity, during his period of debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Mr. Kokes, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Kokes during his period of debarment.

Any application by Mr. Kokes for termination of debarment under section 306(d)(4) of the act should be identified with

Docket No. 01N-0539 and sent to the Dockets Management Branch (see ADDRESSES). All such submissions are to be filed in four copies. The public availability of information in these



submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 3/28/03
March 28, 2003.

~~for~~ ~~Janet Woodcock~~ Steven K. Galson,
Deputy Director, Center for Drug Evaluation and Research

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL
Dawn P. Hawkins